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TITLE: Caring Letters for Military Suicide Prevention: A Randomized Controlled Trial

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14. ABSTRACT The purpose of this multi-site study is to conduct a Department of Defense (DoD) Telemedicine and Advanced Technology Research Center (TATRC) funded randomized controlled trial of the Caring Letters intervention to determine if the intervention is effective in preventing suicide and suicidal behaviors among Service Members and Veterans. The "caring letters" concept was originally developed and evaluated by Jerome Motto and colleagues in the 1970's (1). In Motto's trial, civilian psychiatric inpatients were sent caring letters following discharge (initially monthly, decreasing to quarterly) for five years. Compared to a control group (usual care) with no further contact, the Caring Letters group had a significantly lower suicide rate for the first two years of the trial. These "caring letters" are one of the only suicide prevention interventions to reduce suicide mortality in a randomized controlled trial. Despite the initial promising results of the original Caring Letters RCT, there have been no published replications of the intervention or tests of the intervention among military personnel or veterans. This study will fill an important gap in the evidence base for the Caring Letter intervention and is timely given the steady increase of military suicide in recent years.					
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Introduction:

The purpose of this multi-site study is to conduct a randomized controlled trial of the Caring Letters intervention to determine if the intervention is effective in preventing suicide and suicidal behaviors among Service Members and Veterans. The “caring letters” concept was originally developed and evaluated by Jerome Motto and colleagues in the 1970’s (1). In Motto’s trial, civilian psychiatric inpatients were sent caring letters following discharge (initially monthly, decreasing to quarterly) for five years. Compared to a control group (usual care) with no further contact, the Caring Letters group had a significantly lower suicide rate for the first two years of the trial. These “caring letters” are one of the only suicide prevention interventions to reduce suicide mortality in a randomized controlled trial (2). Despite the initial promising results of the original Caring Letters RCT, there have been no published replications of the original intervention or tests of the intervention among military personnel or veterans. This study will fill an important gap in the evidence base for the Caring Letter intervention and is timely given the steady increase of military suicide in recent years.

Body:

The team submitted continuing review for Tripler Army Medical Center to MAMC IRB on 16 April 2015 and was approved through 23 June 2016. Continuing review was submitted to MAMC IRB for Landstuhl Regional Medical Center on 05 May 2015 and was approved through 23 June 2016. Continuing review was submitted to MAMC IRB for Madigan Army Medical Center on 05 May 2015 and was approved through 23 June 2016. Continuing review was submitted to MAMC IRB on 07 May 2015 for Naval Medical Center San Diego and was approved through 23 June 2016. Continuing review was submitted to Stanford IRB for Palo Alto and was approved through 31 March 2016. Continuing review was submitted to Buffalo VA Medical Center IRB for VA Western New York and was approved through 23 October 2016.

Continuing review was submitted to HRPO for TAMC and NMCSD on 08 July 2015.

Continuing review was submitted to HRPO for VAPA on 27 July 2015.

Continuing review was submitted to HRPO for MAMC on 04 August 2015.

On 12 November 2015, received HRPO acknowledgment for VA Western New York.

A No Cost Extension request was submitted on 03 November 2015 for an extension of the period of performance until 27 February 2017. Approval was received on 27 January 2016.

Key Research Accomplishments:

Administrative and Logistical Matters

1. Personnel
 - a. The coordinator at MAMC went from 50% effort to 100% on 01 December 2015. The coordinator at LRMC resigned and her last day was 11 December 2015, and the MAMC coordinator will complete the follow-up procedures for LRMC. A project manager was hired at the main site and all necessary training was completed.
2. Equipment
 - a. None required at this time.
3. Materials, supplies and consumables
 - a. Materials and required supplies continue to be coordinated in anticipation for data collection and future archive and close-out procedures.
4. Institutional Review Board (IRB)

- a. MAMC IRB continuing review approved through 23 June 2016.
(MAMC, TAMC, LPMC and NMCSO)
- b. VA Palo Alto continuing review approved until 31 March 2016.
- c. VA Western New York Buffalo approved until 23 October 2016.

Amendments:

On 03 November 2015, MAMC IRB approved additional back-up research monitor of LCDR Valerie Littlefield, PMHNP at Navy Medical Center San Diego.

On 28 January 2016, change of information for sub-investigator and removal of a sub-investigator submitted to MAMC IRB.

On 11 February 2016, approval received from MAMC IRB for the addition of collaborating staff and removal of one staff member.

Recruitment & Enrollment:

All 6 sites have completed recruitment and enrollment of participants. A total of 1, 319 participants are enrolled in the study.

Follow-ups are currently taking place at all six sites.

Submission of Serious Adverse Events:

At VAPA three SAEs were reported. One SAE was reported and acknowledged on 23 September 2015. The cause of death was amphetamine intoxication complicating a cardiovascular condition, not study related. One SAE was reported and acknowledged on 20 November 2015. This was a suicide not related to the study. One SAE was reported on 23 November 2015 for Palo Alto VA. The cause of death was blunt force trauma not related to the study.

At NMCSO one SAE was reported and acknowledged on 26 May 2015. The cause of death is unknown and not related to the study.

Internal Audits:

Ms. Lisa Thomas conducted a site audit at LPMC the week of 19 June 2015 and there were no significant findings.

Amy Holstein, Human Protection Administrator at LPMC, conducted an audit on 24 June 2015 with no significant findings.

Ms. Karyna Boykin conducted a site audit at NMCSO the week of 13 July 2015 and there were no significant findings.

Ms. Karyna Boykin conducted a site audit at the Palo Alto VA site the week of 26 Oct 2015 and there were no significant findings.

AHRPO conducted an audit of the Caring Letters project at MAMC on 28 October 2015 and as a result there were no findings.

Presentations:

Kolade, L., Shere, L., Gill, S., G. Saini, G., MacRae, F. Kuppuswamy, M., Relova, R. M., Lee, T., & Luxton, D. D. (2015, March). Post-hospitalization Caring Contacts for Suicide Prevention Provide Active Crisis Intervention Benefit at VA Palo Alto. Society for the Advancement of Violence and Injury Research. New Orleans, LA.

Luxton D. D. (2015, June). Caring Emails for Military Suicide Prevention. In D. D. Luxton (Chair), Post-Treatment Technology-Based Caring Contacts for Suicide Prevention. 28th World Congress of the International Association for Suicide Prevention, Montreal, Canada.

Final Data Collection: Final outcomes assessments have begun at all sites. Anticipated final follow-up data collection date is 31 December 2016.

Reportable Outcomes:

None

Conclusion:

None

References:

1. Motto JA, Bostrom AG. A randomized controlled trial of post-crisis suicide prevention. *Psychiatry Serv.* 2001; 52(6):828-833.
2. Luxton, D. D., June, J. D. & Comtois, K. A. (2013). Can Post-Discharge Follow-up Contacts Prevent Suicide and Suicide Behavior?: A Review of the Evidence. *Crisis: The Journal of Crisis Intervention and Suicide Prevention.* 34, 32-41.

Appendices:

None